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Research Center

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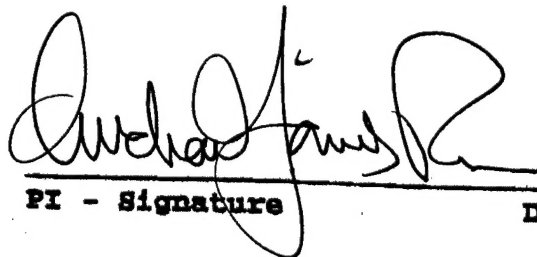

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A. Introduction

In this report, we provide status information on a number of projects that began and/or were carried out by the National Rehabilitation Hospital's Assistive Technology Research Center (ATRC) in year four of our cooperative agreement #DAMD17-94-V-4036. This document also contains continuation plans for year 5 in which we were granted a no cost extension to complete pending projects.

ATRC activities are directed by a senior management team comprising Michael Rosen, Ph.D. and Joseph Bleiberg, Ph.D., co-principal investigators; John Toerge, D.O., medical director of the ATRC; Jack Winters, Ph.D., director of Catholic University support for the ATRC; Tom Dang, MSE, manager of the rehab engineering; and Sabrina Smith, MHA, grant manager of the ATRC. This group meets regularly to review progress on the ATRC goals and objectives.

The ATRC is divided into two main components: the Assistive Technology Transfer program and the Cognitive Performance Enhancement program. This report will reflect upon activities carried out by each of these programs and will discuss future projects charted for continuation of this cooperative agreement.

**Projects based in the
Rehabilitation Engineering Service**

Biomechanical Analysis of Scott-Craig Type Long Leg Braces During Ambulatory Tasks

Project Number: 1 Status: Closed

Principal Investigator: Tom Dang

Co-investigators: John Noiseux, Brad Blaise, Joyce Luncher*

Person-months committed: 7

Project Abstract:

The aim of this project is to obtain a quantitative understanding of the mechanical loading of the Scott-Craig type long leg braces during various ambulatory and functional tasks. Two goals of this study were to provide information to both the orthotic industry to address the issue of over-design and to the composite brace research team (Project 2) to possibly assist with the development of nonmetallic composite brace components.

In the past, several knee-ankle-foot-orthosis (KAFO) designs have been evaluated objectively. These studies, however, only examined a few load components, and provide a very limited view of overall loading patterns.

The focus of this study was to answer the question: "How are stresses distributed throughout the Scott-Craig long leg brace components during ambulatory activities?"

Year 4 Progress and Outcomes:

For year 4, the research team (which lost team members Joyce Luncher and Brad Blaise)* completed the analysis of the data sets from the four subjects. Stress data from three subjects was reduced and analyzed from the strain gage information. The highest stresses measured were not consistently located at any one site (even within any single subject's data). It was, however, noted that the above-ankle site was the most frequent site of high stress. This was consistent with physical reasoning and comments by orthotists indicating that a frequent site of brace failure is at the ankle joint. Large variations in maximum stresses were noted both among subjects, and among repetitions of identical tasks by the same subject. The highest stresses were recorded during the up- and down-a-step tasks, but stresses over 100MPa were recorded even during gait trials. The highest stress recorded during the study was approximately 138 MPa, due to Medial-Lateral loading. This occurred during the down a step task, at the below knee site.

Variations in stress influenced by many factors, among them patient height and weight, the customized shape of each user's brace uprights, proficiency and functional ability of the walker, and walker's fatigue.

The above findings were presented at two conferences in year 4. The results of the study were presented at MRI '98 Research Day in D.C. and RESNA '98 in Minneapolis, MN.

*Mr. Blaise and Ms. Luncher left the ATRC staff to assume positions elsewhere mid-year.

Clinical Study of Injection Molded Composite Ankle Joint Component of NRH Brace

Project Number: 2a

Status: Year 5 will bring project to a close

Principal Investigator: John Noiseux

Co-investigators: Tom Dang, Fatemeh Milani (NRH physiatrist), Ginger Walls (NRH PT)

Person-months committed (with Project 2b): 1.5 (of ATRC engineering staff)

Progress in Year 4:

In year 4 the clinical trials of the second generation of the composite Ankle joint component, the Long Fiber Injection Molded (LFIM) composite Ankle joint, were completed. This entailed the joints being incorporated into a pair of Scott-Craig long leg braces, and the braces being utilized in swing-through gait and other tasks (practice falls, etc.) for a total of 50 hours. The LFIM ankle joints were returned to Sparta, Inc. for post-clinical trial analysis. Sparta's testing indicated that the LFIM composite ankle joints exceeded the design moment (548 in-lbs) but fell short of the design load of 220 lbs by approximately 15%. The post-clinical LFIM joint tested in cyclic loading met the criteria of being loaded from 10 lbs to 110 lbs for 1 million cycles.

At this time no further development of the LFIM composite ankle joint is being pursued. The current LFIM composite ankle joint meets the cyclic loading and moment criteria and withstood approximately 85% of the static loading criteria. As these criteria are demanding, the current design will be considered in development of the Becker commercial brace (see below).

Clinical Study of Composite Footplate Component of NRH Brace

Project Number: 2b Status: year 5 will bring the project to a close.

Principal Investigator: John Noiseux

Co-investigators: Tom Dang, Fatemeh Milani, Ginger Walls

Progress in Year 4:

The composite footplates went through two design revisions during year 4. Changes were made to improve ease of installation for orthotists and to increase strength. Changes include: angling the front portion of the footplate and thickening of the pocket that receives the stirrup portion of the footplate. The footplate was angled in the plantar direction (downward) to minimize the post-forming task performed by the orthotist to incorporate the footplate into a shoe. The thickening of the pocket improves the strength of the footplate. Results from pre-clinical testing indicate that the latest prototype composite footplate can withstand the design moment of 1046 in-lbs. It is presently being tested against the load criteria of 220lbs. The current design of the composite footplate has been submitted for evaluation to Becker Orthopedic, the orthotics manufacturer which has been a partner in this project from its inception.

Proposed Work and Outcomes for Year 5:

This project will come to a close in year 5 with transfer of primary responsibility to Becker Orthopedic. That firm will utilize the outcome of the work to date as a component of an ultra-lightweight long leg brace (or brace component system) which they expect to weigh half as much as current products. After clinical trials at NRH, involving orthotics vendor Nascott, Becker expects to roll out their new line in April of 2000.

Endoprosthetic Replacement Surgery for Distal Femoral Sarcomas: Identification of Functional Outcome Variables and the Development of a Preliminary Knee Model for Presurgical Planning

Project Number: 3

Status: Closed

Principal Investigator: Tom Dang

Co-investigators: Justin Carter, Melanie Brown

Person-months committed: 2 (including Dr. Brown)

Project Abstract:

The objectives of this study are, 1) to identify biomechanical function variables that best correlate to functional outcome measures as defined by the MSTS evaluation protocol for limb sparing procedures, and 2) to evaluate the feasibility of using a 3-D model of the knee to predict biomechanical function (related to functional outcome) variables in patients who have undergone the limb-sparing procedure for femoral osteosarcomas. Isometric tests were conducted to evaluate actual knee function along with kinematic and kinetic data obtained using the VICON 3-D motion analysis system. Functional tasks under investigation were a) level walking; b) stair ascending and descending; c) standing on one foot; and d) sit-to-stand. Data was analyzed to discern patterns of compensatory strategies.

Year 4 Progress and Outcomes:

In year 4, we reduced and analyzed data for 7 subjects who had undergone distal femoral limb salvaging procedures. The research team decided to analyze only the sagittal-plane data for all the subjects. A simple one-way ANOVA was used to compare the average across trials within subject's intersegmental angles and moments generated by the affected limbs during level over-ground ambulation to those generated by the unaffected limbs. The results were presented at ISOLS '97 and ASB '97 conferences.

After completion of the data analysis of 3-D kinematic and kinetic data, comparisons with strength test data were done to determine any correlation between strength and gait. Unfortunately, no correlation between the two data sets was identified. The research team believes that inconsistencies in the limb sparing procedures between subjects resulted in varying strength outcomes.

Continuation plan in brief:

For year 5, the research team will publish the results of the study in an orthopaedic journal such as Orthopaedic Research Society.

Biofeedback/Augmented Therapy

Project Number: 4

Status: Continuing

Principal Investigator(s): Tom Dang, Dr. Katherine Alter

Co-investigator(s): David Brennan, Melanie Brown (consultant)

Person-months committed: 4

Project Abstract:

In year 4, a pilot study titled, "Video Games for Lower Extremity Strength Training in Pediatric Brain Injury Rehabilitation," was planned. The objectives for this study were: 1) increase lower extremity muscle strength and control in children with brain injury using video game enhanced therapy, 2) demonstrate that muscle strengthening improves function, and 3) demonstrate that functional improvements are significantly greater when video game exercise programs are used in addition to conventional rehabilitation programs.

In the study, children with brain injury who participate in a conventional rehabilitation program are asked to use a video game driven from processed surface EMG for thirty minutes, three times per week to strengthen the weak muscles in their lower extremities. Baseline functional status and changes in functional status are evaluated using a number of qualitative and quantitative methods. Traditional tests such as manual muscle evaluations and clinical questionnaires are administered by clinicians and used to evaluate functional status. These evaluations are supplemented with temporal spatial, kinematic, kinetic, and EMG movement analysis data obtained at the ATRC.

Year 4 Progress and Outcomes:

Both MRI and the Department of the Army granted IRB approval in September of 1997. Discussions between the research team and therapists brought two main problems to light: the current IRB approval applied only to subjects tested at NRH, and the functional outcome measures (improved values of gait parameters) were slightly unrealistic. It was decided that a more realistic outcome measure would be improved strength of the targeted muscle groups. The protocol was also modified to use isometric muscle strength rather than surface EMG signals to control the video game. The video game interface was renamed the Interactive Video Exercise System (IVES). The IVES prototype consists of a Rifton Advancement Chair fitted with a single-axis force transducer to measure isometric knee extension force. The Rifton chair gives total body support during subject testing and allows for the targeted muscle to be isolated, promoting greater exercise efficiency. The force transducer used is capable of measuring loads up to 250 lbs., well within the range of forces generated by the target population. IVES was demonstrated at the RESNA '98 conference in Minneapolis, MN.

Continuation plan in brief:

For year 5, the research team proposes to complete a pilot test (ten subjects) of the modified systems and test protocol. The IRB applications have been amended and will be resubmitted for approval. The research team will coordinate with one or two local private physical therapy practices to conduct the pilot testing of IVES. Patent and/or marketing avenues will also be investigated with the goal of making IVES a take-home therapy product.

Assessment of Unilateral Spatial Neglect in a Virtual Reality Environment

Project Number: 5

Status: Closing

Principal Investigator: J. Carter

Co-investigators: J. Luncher*, S. Kodgi (Physiatry resident), B. Conroy, W. Garmoe

Person-months committed: 2.5 (of ATRC engineering staff)

Project abstract:

The aim of this project is to develop and assess the efficacy of a VR-based diagnostic tool for patients with unilateral spatial neglect. Subjects from each of the three groups (stroke with neglect, stroke-only, and control) participated in a virtual reality simulation in which they were asked to point to the center of various cylinders presented to them while wearing a head mounted display (HMD) and instrumented glove. Data analysis indicates that there is a difference in performance among the three groups, but the analysis is too preliminary at this writing to draw any conclusions.

Year 4 Progress and outcomes:

Not all the work planned for Year 4 was completed. Several methods for data analysis were planned, and some have been implemented. A program was written in C code which eliminates the first 200 milliseconds of data (to account for tester reaction time), checks various criteria to determine whether the trial was legitimate, iteratively calculates the percentage of the data set that should be used for determining a final value, and calculates the final value of hand position. Data analysis was begun and some significant results (differences in performance based on the particular cylinder presented) were found. However, there is more reduction and analysis to be done. This work was continued into the no-cost extension period for completion due to the loss of the co-investigator who was to have a major role in the data reduction.

Continuation plan in brief:

The remaining reduction (which will include different reduction methods and outcome measures) will be completed and the results analyzed. The goal of these analyses will be to determine which of the cylinder locations / stimuli combinations elucidate a difference between the neglect group and each of the other two groups.

The Development and Evaluation of Alternate Educational Strategies for Families of Patients with Unilateral Spatial Neglect

Project Number: 6

Status: Technology Transfer

Principal Investigator: J. Carter and K. Byers (consultant)

Co-investigators: J. Luncher, P. Fletcher (SLP), M. Richman (SLP), B. Conroy, W. Garmoe

Person-months committed: 1.5 of ATRC engineering staff

Project abstract:

The aim of this project is to develop and assess the efficacy of a VR-based educational tool for family members of patients with unilateral spatial neglect. Subjects (the family members) were randomly assigned to one of three study groups and educated about neglect, and their knowledge about neglect was assessed over time by means of three questionnaires. Preliminary results indicate that the group who participated in the VR simulation and the group who watched the custom made video tape fared substantially better than the control group.

Year 4 Progress and outcomes:

Year 4 activities consisted of collecting data from more subjects and starting data reduction and analysis. The final questionnaire is collected 3 months after the initial enrollment, and we have complete data from 23 subjects, 8 from the VR group, 7 from the video tape group, and 8 from the control group. Preliminary analysis of the data from these 23 subjects shows that immediately after either participating in the VR simulation or watching the video tape, subjects in these two groups fared better on the questionnaire with the video tape group doing slightly better. However, three months later, subjects from the VR group fared slightly better. Thus far there has been no statistical significance (nor do we expect any due to the small sample size) and the results from the VR and video tape groups have alternated in terms of higher questionnaire scores.

Continuation plan in brief:

This project was expected to continue through April 1999 and due to the loss of co-investigator Luncher, it may continue a bit longer. Subject recruitment and enrollment should still be complete by April, with data reduction and analysis continuing for an additional three months. Plans are being made for technology transfer to a start-up firm specializing in health education applications of VR.

Surgical Excision of Lower Extremity Soft Tissue Sarcomas: Ability of a Computer Model to Predict Deficits in Strength and Function

Project Number: 9

Status: New

Principal Investigators: J. Carter and Dr. M. Malawer (WHC orthopedic oncologist)

Co-investigators: T. Dang, D. Brennan, B. Blaise Dr. R. Henshaw (WHC orthopedic oncologist)

Person-months committed: 8 (of ATRC engineering staff)

Project abstract:

The aims of this project are 1) to use isometric strength testing data from individuals who have undergone surgical removal of tumors in the leg to validate the strength predictions made by SIMM (an existing computer model); and 2) to use gait analysis techniques to check whether surgically related changes in strength result in significant changes in functional ability (walking). Subjects for this project are assigned to one of four groups based on the anatomic site of their resection: posterior calf, anterior thigh, posterior thigh, or medial thigh.

Year 4 Progress and outcomes:

Data has been collected from 10 subjects and data reduction has begun. These 10 subjects are comprised of 7 from the posterior calf group (we had wanted 10), and 3 from the anterior thigh group (we are currently recruiting more subjects for this group). Strength and gait data from the first 7 subjects have been reduced and analysis has begun. The loss of one staff member, who was to perform the majority of the data reduction, shifted the data reduction process into the current no-cost extension period.

Continuation plan in brief:

The next step, in addition to collecting gait and strength data from subjects, is to modify and analyze an existing computer model. We will use the Software for Interactive Musculoskeletal Modeling (SIMM) and its predictions for individual muscle strength for this purpose. We will also continue and complete data collection from the anterior thigh group before moving on to another group.

Boing! — a Home Exercise Arcade for Children with Disabilities

Project Number: 15

Status: New

Principal Investigators: Dave Brennan, Joyce Luncher

Co-investigators: Mike Rosen, Melanie Brown (consultant)

Person-months committed: 11.5

Project abstract:

Children with disabilities are often limited in their recreation and physical activity which, in turn, can diminish their fitness level, social development and self-esteem. The Boing! Exercise Arcade was designed to address these concerns by providing fitness, fun, and social interaction. Boing! serves as a multi-purpose home gym for children in which resistance and aerobic exercises of any part of the body are performed in the context of video games that entertain and motivate.

Year 4 Progress and outcomes:

The evaluation of the original Boing! prototype was completed at the Campbell Clinic in Germantown, Tennessee. Gary Downey, a Master's student at the University of Tennessee, Memphis who had been working on Boing!, finished his thesis and received his degree in June. Boing! was awarded a Paralyzed Veterans Of America Design Award at the RESNA 98 conference in Minneapolis. The current prototype was shipped to the ATRC in late June. It was reassembled in the lab where it presently stands. A student intern during the summer began work on the pulley system in an attempt to minimize binding of the bungee cord and minimize hysteresis and delay in the translation of limb motion to motion of the video game icons. A steering wheel prototype was fabricated as the interface to a driving game, and investigation into alternatives for the Bogen articulated arms which support the bungee pulley and the video monitor was begun. Two of the four staff members (Joyce Luncher and Melanie Brown) who had been working on this project left the ATRC midway through the year, which slowed progress somewhat and required continuation into the present no-cost extension period.

Continuation plan in brief:

A complete design evaluation of the Boing! prototype will likely yield design changes including an ultra-low-friction pulley system, articulated support arms whose locking joints will sustain higher loads, a custom monitor mount, and an improved bungee translation transducer. A second generation prototype will be fabricated and evaluated in a pediatric rehabilitation setting to be determined. A protocol will be established for collecting data on its efficacy in meeting therapeutic goals as well as reactions of therapists, children and their families. Patent and/or marketing avenues will also be investigated with the goal of gaining interest from a manufacturer for marketing and commercialization. Boing! will be also be incorporated into the Teleplay development activity of the Telerehabilitation RERC as an interface to virtual collaborative environments and embedded teleassessment activities.

Ani-Mate: a Software Environment for Creating Custom Video Games for Use with Boing!

Project Number: 16

Status: New

Principal Investigator: Justin Carter

Co-investigators: Dave Brennan, Tom Dang, Mike Rosen

Person-months committed: 3

Project abstract:

To succeed as a product, Boing! will need to rely on a library of animated games which will be sufficiently engaging to motivate children with a variety of capabilities and needs to exercise. Ani-Mate, a video game authoring tool with which a person with no specialized knowledge of computers can craft individualized animated computer games, will allow therapists and parents to create *custom* games for each user that may include favorite objects, situations, characters, music, etc.

Year 4 Progress and outcomes:

The video games that accompanied the Boing! prototype (written by Dr. Stan Cronk at the University of Tennessee in Memphis) were received early in the year and were evaluated as a means of learning the Director software package with which they were written. Two additional simple games were written (Soccer Kick, Balloon Blow) to demonstrate the potential of the system. Summer interns then considerably expanded the library of Ani-Mate games to include:

- Dunking booth - limb extension throws a ball at a dunking booth
- See-saw - user "bounces" up and down to move the see-saw
- Frogs - click the "big red button" to extend the frogs tongue and catch flies
- Turtles - limb extension moves a net to catch turtles in a river
- Race car - steering the car changes lanes, the "big red button" changes gears

A preliminary user interface was developed in which the users would be characterized in terms of game preferences and limitations (favorite objects, sound tolerance, favorite movies, exercises required, etc.).

Continuation plan in brief:

The existing video games will be modified so that objects, movies, and sounds can be easily adjusted, swapped, and modified as needed while retaining the original rules of a game. A database of these moveable objects and targets will be created. The prototype professional's interface will be developed and evaluated by clinical colleagues at NRH.

Wired Independence Square

Project Number: 19

Status: New

Principal Investigator: B. Blaise, Justin Carter

Co-investigators: V. Gupta, A. Fu, J. Luncher

Person-months committed: 6

Project abstract:

Recently installed at NRH, Independence Square (IS) is a mock-up of everyday living spaces and is used by therapists to train patients in adapting to environments which they will regularly encounter after they are discharged. Traditionally, evaluation of a patient's performance during training is subjective (even when numerical rating scales are used, e.g. for FIM), and therefore sensitive to inter-rater variability and characterized by limited resolution and shifting calibration. Our desire, therefore, is to implement a sensor-based system in IS that will permit therapists to capture objective measures of the performance of a patient during her/his training, measures which have "ecological validity" since they are based performance of activities of daily living.

Year 4 Progress and outcomes:

The portion of Year 4 in which this project was active has been spent planning and making preliminary demonstrations of the concept. ATRC project members met regularly with staff members from the OT, PT and SLP Services to ensure that the project maintains a direction that is useful to therapists – the professionals who will use the system. We chose the kitchen as the room in which we will start and selected tea-making to evaluate our data collection and display.

We have amassed several types of sensors (magnetic reed, infrared beam, flow, etc.) whose efficacy we will investigate. Currently we have installed magnetic reed switches on the refrigerator, one cabinet, and one drawer, a flow sensor on the cold water tap in the sink, as well as a microswitch on one burner of the stovetop, an infrared beam across the entryway, and a camera mounted above the stovetop. In addition, we have experimented with different software packages and methods to display the results. We are displaying the data (which is collected using LabVIEW and plotted using MS Excel) using MS Visual Basic. This will be the software used to design the interface through which therapists will interact with the system. We have shown the results in graphical form as well as in a more pictorial display. The final display will depend heavily on therapists' preferences. The major technical challenge we have yet to overcome is that of patient identification. When there is more than one patient being assessed in the kitchen at one time, we do not yet have a way of recording which patient activated which switch. We investigated the TIRIS system (used in the Mobil Speed Pass commercial application) among others) but found it to be cost prohibitive. The current state of the project was demonstrated with the task performed in IS at NRH and the data sent and displayed at a location in California.

Continuation plan in brief:

In the next several months, we plan to zero in on a more final sensor selection, as well as to find a method to establish patient identification. We will continue to investigate the AMPS (Assessment of Motor and Process Skills) protocol to determine its value to this project. We will use the AMPS to help develop a theoretical framework for the assessment of future task designs.

This project is now jointly funded by the ATRC and the recently awarded Telerehabilitation RERC, and as a result, goals have been extended to include at-home installations.

Virtual Reality Display and Gaze Monitoring to Investigate Acquired and Congenital Impairments of Visual Processing

Project Number: 20

Status: In progress

Principal Investigator: Cheryl Trepagnier

Co-investigators: Marc M. Sebrechts, Joseph Bleiberg, Benjamin A Knott, Vineet Gupta, Stephanie Johnson.

Other Personnel: Kris Chrishon

Person-months committed: 4

Project abstract

Impairments in face processing have been identified in persons with autism spectrum disorder. Persons with right hemisphere stroke display impairment of global processing as well as left neglect in some cases. This study undertakes evaluation of gaze behavior of groups representing these two populations in tasks involving faces and objects presented using virtual reality display, when stimuli are presented upright or rotated. Data is acquired using the gaze-sensing technology installed in the virtual reality head-mounted display helmet.

Year 4 Progress and Outcomes

The project was approved by NRH and MRI and approved by the Army IRB in October of 1998. The eye-tracking calibration has been the object of testing and it has been determined that there is a need to screen patients for deficits of stereoscopic vision, as strabismus has effects on calibration. A test of strabismus is being ordered.

Stimuli are being prepared using stereoscopic photography of faces and of objects and the experimental design has been refined. The first version of the software for presentation of the stimuli, management of the study and data acquisition was completed in December of '98.

Adjunct funding was obtained for this project through the NIDRR Rehabilitation Engineering Research Center (RERC) on Telerehabilitation, as of October 1, 1998. This competition focused on applications of telecommunications to rehabilitation, and also called for submission of projects using Virtual Reality. Components of Project 20 were submitted as part of that application, specifically additional coverage of the principal investigator's time, in order to accelerate the progress of this research.

With the successful outcome of the RERC application, resources from the ATRC no-cost extension have been reallocated. The level of effort of the principal investigator has been increased, and the principal investigator has accomplished the training required for use of the Autism Diagnostic Interview-Revised (tm), and acquired the materials necessary for use of the Autism Diagnostic Observation Scale. These are gold-standard autism diagnostic instruments.

Progress during the no-cost extension: Informal trials involving ten non-disabled individuals have been carried out. This has led to a number of modifications in the physical characteristics of the study, in order to raise the proportion of individuals for whom calibration and accurate eye-tracking data can be obtained. (1) It was determined that there was a need to modify the stimulus characteristics. It was found that too high a level of light in the stimuli impairs eye-tracking accuracy due to the reduction in pupil size. When pupil size is decreased, the sensors may track other reflective areas instead of the pupil. It was not possible to remedy this by manipulation of the images ('painting' the background) and still obtain satisfactory image quality. Accordingly, the photographs of non-face objects for the task, which had been taken on a light background, are

being re-taken. (2) It was also determined that modifications were needed to permit greater stabilization of the headset without impairing comfort. Shifting of the headset in the course of the study caused the tracking to become inaccurate. Padding of the headband makes it possible to tighten the headband comfortably. Support for the cable coming off the headband reduces the tendency to shift. (3) The third modification involves reducing and raising the area of interest in the field of view. Calibration was found to be consistently more accurate when the individual was looking up than when individuals were looking downward, due to effects of lowered eyelids. Images and the calibration routine were moved so that gaze is tracked only in the upper part of the viewer's field of vision.

It should be noted that these measures are dictated by the need of the experiment for resolution that will distinguish whether individuals are looking at the eye area versus the hairline, or the eye-area versus the mouth. Direction of gaze in terms of quadrant of the field, or even whether the viewer is looking at the upper or lower face, is obtainable with high accuracy without these modifications.

Pilot data has been obtained with one adult with autism and one non-disabled adult. These data are consistent with our expectation that the recognition task is pitched at an appropriate level of difficulty for our populations of interest. On the one hand, the highly capable adult did not ceiling on the task. In terms of whether the task is within the ability level of persons with autism, the pilot subject achieved a high score, comparable to that of the non-disabled individual, in terms of recognition of non-face stimuli, while scoring correctly on only half the face items (17 / 32).

The rationale and design of the study and preliminary data were presented as part of an hour-long presentation at the California State University at Northridge conference, Technology and Persons with Disabilities, March 19, 1999.

Continuation Plan

The modifications described above are expected to be completed by May 30. Three individuals with right hemisphere stroke and three with autism will be enrolled as pilot subjects to assure that the accuracy of eye tracking is adequate to capture behavioral differences. It is anticipated that the pilot trials and analyses will be complete by July 30, 1999. Data collection will begin once the pilot data are analyzed.

Magic Walker Brake Development

Project Number: 22

Status: New

Principal Investigator: John Noiseux

Co-Investigator: Mike Rosen

Project Abstract:

The Magic Walker was designed at the University of Tennessee. It is gait trainer and ambulation aid that provides a child with support in an upright standing position. The child's weight is partially born on the walker seat and partially supported by the child's legs. The amount of support received can be customized based on the needs of the child. Steering of the walker is achieved by flexion of the trunk laterally. The coupling of steering to lateral trunk flexion leaves the upper limbs free for manipulation and play tasks. The utilization of trunk control for steering and the less confining frame design are what distinguish this design from other gait trainers/walkers. The main objective of the Magic Walker Brake Development project is to incorporate an automatically deploying brake system into the present design. This will be essential for safety in outdoor use and should increase the marketability of the design.

Progress in Year 4:

Construction of a Magic Walker based on a design developed at the University of Tennessee has been completed. Modifications to the original design include the use of a flexible push-pull cable to replace pushrods and one of the bellcranks in the transmission which drives steering from torso movement. This reduces the number of parts, and eliminates a rod end bearing that was susceptible to binding due to contamination from saliva and food from users that drool. Initial design concepts for brakes have been explored, with several being eliminated (e.g. centripetal and caliper brakes). A potential user has been identified for the first walker constructed at NRH. It is anticipated that this user (currently recovering from surgery) will begin using the unit in early 1999.

Proposed work in Year 5:

In year 5 brake operating conditions will be completely defined and prototype braking mechanisms will be built and evaluated in the lab and in use. In addition, a small number of additional Magic Walkers will be fabricated. These units will be utilized to test brake system prototypes and gain additional insights from a user's perspective.

**Projects based in the
Psychology Service**

Efficacy of Ginkgo Biloba (EGB 761) for Enhancing Neuropsychological and Daily Functioning after Stroke

Project Number: 1

Status: Ongoing Years 5-6

Principal Investigator: Joseph Bleiberg, Ph.D. and Jeffrey Campodonico, Ph.D.

Co-Investigators: Brendan Conroy, M.D., William Garmoe, Ph.D., Judith Gray, R.N., N.P., and Fatima Milani, M.D.

Project Abstract:

This FDA-approved phase 3 clinical trial examines whether pharmaceutical grade ginkgo biloba extract enhances recovery of neuropsychological functioning and activities of daily living in persons who have suffered a recent cerebrovascular accident. The study is a six-month, double-blind, randomized, placebo controlled, parallel group clinical trial with a total sample size of approximately 550. Indices of efficacy include neuropsychological functioning, performance of daily functional activities, general medical health, psychological well-being, and quality of life. These indices are assessed prior to initiation of treatment and at eight weeks and six months post onset of treatment.

Year 4 Progress and Outcomes:

Year 4 activities consisted principally of completing the FDA process for an investigational new drug application. The original 1997 DOD IRB review of this project stipulated that an IND application, approved by the FDA, was a requirement for approval of this project. Shortly after the DOD IRB informed us of this requirement, an EGB 761 trial in Alzheimer's patients was published in the Journal of the American Medical Association. Representatives from the Schwabe Co., the German manufacturer of EGB 761, were in the U.S. at the time to attend the press conference regarding the positive results in the Alzheimer's trial, and we took the opportunity to meet with Schwabe officials and enlist their support in our study. Schwabe agreed to supply both EGB 761 and placebo for our study and to submit all necessary FDA documentation for the IND application. In January of 1998 Schwabe shipped us 200,000 EGB 761 tablets and 200,000 placebo tablets, which currently are in temperature controlled storage. Schwabe also has submitted all required documents and toxicology data to the FDA, and we have been contacted by the FDA and are scheduled for a conference call with them on November 12, 1998 to obtain their response to our application.

Continuation Plan:

We are prepared to commence the study once we receive official FDA approval. The project already has been approved by the Medlantic Research Institute and DOD IRB's. In anticipation of the delay introduced by the IND process, we arranged in writing with the DOD for a one-year extension of this study and for approval to carry unexpended Year 4 funds into Year 5. The only modification from the existing plan is that we may seek a second site for conducting the study in order to accelerate accrual of the required subject sample.

While the focus of our study is on cognition and behavior, we also recognize that our study will create experimental samples useful to researchers interested in EGB 761's effects on vascular, hematological, and functional neuroimaging variables. We currently are seeking collaborators from these disciplines from our campus and the broader scientific community.

Sports Concussion Study (and)

Psychometric Properties of Automated Neuropsychological Assessment Metrics (ANAM)

Project Numbers: 2 and 4

Status: Ongoing Years 5-6

Principal Investigator: Joseph Bleiberg, Ph.D. and William Garmoe, Ph.D.

Co-Investigators: Jeffrey Campodonico, Ph.D., Dennis Reeves, Ph.D., and Robert Kane, Ph.D.

Project Abstract:

This originally was a prospective study to identify high school athletes suffering sports concussions and to follow them closely to identify the natural history of recovery. By Year 4, the number of concussed subjects remained too small to permit meaningful study of the original question. However, we had collected standardized neuropsychological test data and ANAM data on over 125 children, a sufficient sample to permit analysis of the psychometric properties of ANAM for this population of children.

Year 4 Progress and Outcomes:

The neuropsychological batteries employed in the study included three standardized clinical tests highly sensitive to the effects of cerebral concussion: the Consonant Trigrams Test, Trailmaking Test Part B, and the Paced Auditory Serial Addition Test, in addition to ANAM data. Moreover, two complete test sessions, separated by two or more months, are available for more than half the sample. This data set can be used to identify the underlying factor structure of ANAM, its test-retest reliability, and the normative expectations for this population of children. Progress during Year 4 consisted of completing data acquisition, entering data into a database specifically written for this function, and designing the data analysis strategy.

Continuation Plan:

We expect to devote the first four months of Year 5 to completing the data analysis. Drs. Kane and Reeves will be contributing additional, independent data sets to be used for confirmatory factor analyses.

One of the main goals of the data analysis will be to identify a brief subset of ANAM tests which share variance and can be substituted for standardized clinical measures sensitive to cerebral concussion. We then will use this as the empirical basis for constructing an ANAM battery specifically designed for maximal sensitivity to cerebral concussion. Unlike the standardized tests which are not designed and are not practical for multiple repeated application, this ANAM battery could be used for repeated administration to closely monitor recovery from concussion in young athletes as well as other youngsters.

The above ANAM battery will then form the nucleus of a new project, one focused on software design and implementation. We will design the new ANAM battery so that it can be automated for convenient administration in the computer laboratories at schools, such that an entire team can be baselined in ten minutes or less. This software will be offered to schools at no charge.

ANAM Database

Project Number: 5

Status: Ongoing

Principal Investigator: Joseph Bleiberg, Ph.D.

**Co-investigators: William Garmoe, Ph.D., Dennis Reeves, Ph.D., Tim Ellsmore, Ph.D.
Robert Kane, Ph.D., and Ellen Halpern, Ph.D.**

Project abstract:

Research using ANAM as a repeated measures test generates enormous quantities of data. It was determined during Year 1 that a centralized ANAM database could greatly facilitate the data reduction and analysis process and facilitate collection of data from colleagues in the ANAM research community. In the latter portion of Year 2, a Microsoft Access database was designed and developed to store the raw ANAM data and associated demographic and neuropsychological test data collected by researchers here at NRH. In Year 3, the testing and demonstration phase included data entry and data management of neuropsychological, psychosocial, demographic, and ANAM data from earlier studies (Variability and Ritalin/Dexedrine), the Sports Concussion Study, several ATRC pilot projects, and from samples provided by colleagues at Baltimore VA (Dr. Kane) and Balboa Naval Hospital (Dr. Reeves).

Year 4 Progress and outcomes:

Several advances in ANAM during Year 4 necessitated rewriting the database to incorporate new and enhanced features within ANAM itself. The original database was designed to accommodate ANAM V. 3.11. During Year 4, we upgraded ANAM to ANAM 2000, and Drs. Kane and Ellsmore developed the Space Cognitive Assessment Test (S-CAT), and we rewrote the database to accommodate the new data formats and additional tests included in these new batteries. The new database began beta testing in July of 1998.

Continuation plan in brief:

The first half of Year 5 will be devoted to developing of the final version of the database. This database also is the backbone for all data analyses in the ANAM projects currently underway. Once the database has been fully tested and is in a stable form, preparations will be made to make it available on a server and ultimately via the World Wide Web. A protocol will be developed to allow the larger ANAM research community to add data to the database and to access the data of others.

Investigation of Grip Constancy as a Behavioral Marker of Concussion and Mild Head Injury

Project number: 7

Status: New and continuing

Principal Investigator: Cheryl Trepagnier, Ph.D.
Co-investigators: Joseph Bleiberg, Ph.D.
Other Personnel: David Brennan, MSE
Person-months committed: 4

Project abstract

Grip force constancy with tone feedback has been found to be impaired in individuals with schizophrenia. It is hypothesized that post-concussion patients, and individuals with autism may also be impaired in this respect. This project attempts to replicate the schizophrenia findings and assess performance of post-concussion and autism-spectrum patients. If we succeed, there is potential for clinical assessment of recovery and enhanced understanding of these disorders.

Year 4 Progress and Outcomes

This project began in Year 4. Consent was obtained from NRH, MRI and from the Army in June, 1998. In order to include schizophrenic participants who are pre-drug treatment, we are collaborating with Dr. Terry Goldberg of the NIMH. Approval of the study there is still pending.

A commercial dynamometer, the Lafayette Instrument Dynamometer was calibrated and found to be insufficiently sensitive to differences at low levels of force. A dynamometer was accordingly designed and built specifically for the project. Software to present the stimuli, run the experiment and acquire the data was designed and produced. The software and the dynamometer were modified on the basis of testing for reliability and for comfort.

Testing using staff volunteers indicated that even after modifications to the grip handle, the force levels and duration of the tasks caused fatigue. After discussion with the author of the study of which this is a replication, task duration was shortened by 20%, and the percentages of maximum force requested in the study were reduced to 15, 22.5 and 30% (from 15, 25 and 35%). The instructions were also modified from the earlier study to reduce overexertion.

Six control subjects have carried out the task. Data for the three constant-force tasks have been evaluated using the Kendall's tau nonparametric correlation to examine effects of force level requested on total time off target and variability (mean standard deviation). The correlation between time off target and force level was .362. Correlation between standard deviation and force was .331. Both were significant at the .01 level (2-tailed). These data included the first 30 seconds of each task, a period of much greater variability, since subjects are attempting to identify the force level that will turn off the tone during some or all of this period. It is expected that excluding the first 30 seconds will result in higher correlations.

Continuation Plan:

Testing of control Ss will be continued and testing of individuals who are post-concussion will be carried out as they become available. Data acquisition from individuals with autism will be carried out in conjunction with their participation in the Virtual Reality and Gaze Angle study, in order to minimize costs associated with transportation and diagnostic testing for autism. As the clinical population is tested, controls will be enrolled.

Stability of Cognitive Performance in Adults with Moderate-Severe Traumatic Brain Injury

Project: 8

Status: Ongoing

Principal Investigators: William Garmoe, Ph.D.

Co-Investigators: Joseph Bleiberg, Ph.D., Anne Newman, Ph.D., and Jeffrey Campodonico, Ph.D.

Project Abstract:

There is disagreement in the literature about the extent to which adults with brain injury display impaired sustained attention and stability of mental performance. This is a study comparing stability of cognitive performance in adults with moderate-to-severe traumatic brain injury (TBI) relative to control subjects. Subjects in both groups will undergo repeated testing using the Automated Neuropsychological Assessment Metrics (ANAM), a computer-administered set of tests of cognitive processing efficiency. The groups will be compared for speed and consistency of performance on ANAM. In addition, two schedules of acquisition training will be compared (Massed Practice = 7 trials/day across four days; Distributed Practice = 3 trials/day across nine days) to determine whether one is superior to the other in achieving stable performance asymptote. Subjects will be re-tested one month following the last training session, to assess delayed retention of ANAM performance.

Year 4 Progress to Date:

Year 4 activities have focused on data collection. TBI subjects are being solicited from the brain injury treatment program at NRH, and controls are being recruited from a local university campus as well as from employees of Medlantic. At this point there have been approximately 13 subjects enrolled in the study out of a total projected sample of 40. The protocol was resubmitted to the appropriate institutional review boards for annual renewal, and has been approved for data collection through 6/99.

Continuation Plan:

The focus will continue to be on data collection. Recent steps have been taken to increase subject enrollment, which has included increased levels of advertising the study on the hospital campus. This has resulted in some increase in response by potential control subjects. Attempts to increase enrollment for TBI subjects will be made by contacting other treatment programs in the area to inform them of the study and inquire about potential appropriate candidates.

Assitive Technology Research Center
National Rehabilitation Hospital
DAMD-17-94-V-4036

Year 5 Carryover Allocation

Salary/Fringe	\$	194,623
Other Direct Expenses	\$	92,125
Indirect Expenses	\$	38,889
Total	\$	<u>325,637</u>

Key Personnel

Bernstein, T.
Blaise, Brad
Bleiberg, J.
Brennan, D.
Campodonico, J.
Carsen, C.
Carter, J.
Conroy, B.
Dang, T.
DeJong, G.
Ellis, C.
Fu, A.
Garmoe, W.
Gibson, D.
Gupta, Vineet
Halpern, E.
Keller,
Knott, B.
Luncher, J.
McCarthy, A.
Noiseux, J.
Nurse-Ginkgo (TBA)
OT (TBA)
Pharmacist
PT (TBA)
PT (Walls)
Research Asst (TBA)
Rosen, M.
Ruffin, C.
Smith, G.
Smith, S.
Toerge, J.